

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

WYETH, 5 Giralda Farms, Madison, N.J.  
07940 and ELAN PHARMA  
INTERNATIONAL LIMITED, Monksland,  
Althone, County Westmeath, Ireland

Plaintiffs,

v.

HON. JON W. DUDAS  
Under Secretary of Commerce for  
Intellectual Property and Director of the  
United States Patent and Trademark Office.  
Office of General Counsel, United States  
Patent and Trademark Office, P.O. Box  
15667, Arlington, VA 22215  
Madison Building East, Rm 10B20, 600  
Dulany Street, Alexandria, VA 22314  
Defendant.

Case: 1:07-cv-01492  
Assigned To : Robertson, James  
Assign. Date : 8/17/2007  
Description: Admn. Agency Review

Plaintiffs Wyeth and Elan Pharma International Limited ("Elan"), for their complaint  
against the Honorable Jon W. Dudas, state as follows:

**NATURE OF THE ACTION**

1. This is an action by applicants of United States Patent Nos. 7,179,892 (the "'892 patent") and 7,189,819 (the "'819 patent") seeking review of the denial of the correct patent term adjustments for these patents by the defendant Director of the United States Patent and Trademark Office ("PTO"). Plaintiffs are seeking a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '892 patent be changed from 462 days to 756 days, and that the patent term adjustment for the '819 patent be changed from 492 days to 722 days.

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

### **THE PARTIES**

3. Plaintiff Wyeth is a corporation organized under the laws of Delaware, having a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

4. Plaintiff Elan is a corporation organized under the laws of Ireland having a principal place of business at Monksland, Althone, County Westmeath, Ireland.

5. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and Director of the PTO, acting in his official capacity. The Director is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154.

### **JURISDICTION AND VENUE**

6. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1361, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

7. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

8. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

### **FACTS APPLICABLE TO ALL COUNTS**

9. Guriq Basi and Jose William Saldanha are the inventors of patent application number 10/388,389 ('389 application) which issued as the '892 patent. The '892 patent is attached hereto as Exhibit A.

10. Guriq Basi and Jose William Saldanha are the inventors of patent application number 10/010,942 ('942 application) which issued as the '819 patent. The '819 patent is attached hereto as Exhibit B.

11. Plaintiffs Wyeth and Elan are the assignees of the '892 and '819 patents, as evidenced by records recorded in the PTO, and are the real parties in interest in this case.

12. Section 154 of 35 U.S.C. requires that the Director of the PTO grant a patent term adjustment in accordance with the provisions of section 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) states that "[t]he Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination."

13. In calculating the patent term adjustment, the Director has to take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

14. Under 35 U.S.C. § 154(b)(4)(A), "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action."

#### **FIRST CLAIM FOR RELIEF**

15. The allegations of paragraphs 1-14 are incorporated in this claim for relief as if fully set forth.

16. The patent term adjustment for the '892 patent, as determined by the defendant under 35 U.S.C. § 154(b), and listed on the face of the '892 patent, is 462 days. (*See* Ex. A at p.1). The determination of the 462 day patent term adjustment is in error in that pursuant to 35 U.S.C. § 154(b)(1)(B), the PTO failed to allow an adjustment for the time exceeding three years after the actual filing date of the '389 application to the date when the '892 patent issued. The correct patent term adjustment for the '892 patent is 756 days.

17. The '389 application was filed on March 12, 2003 and issued as the '892 patent on February 20, 2007.

18. Under 35 U.S.C. § 154(b)(1)(A), the following periods of time are attributable to PTO examination delay:

- a. A period of 559 days under 35 U.S.C. § 154(b)(1)(A)(i) due to failure by the PTO to mail an action under 35 U.S.C. § 132 not later than 14 months of the actual filing date of the application (*i.e.* by May 12, 2004).
- b. A period of 51 days under 35 U.S.C. § 154(b)(1)(A)(iv) due to the failure of the PTO to issue the '892 patent within four months after the date the issue fee was paid ("4 Month Issue Delay").

- c. Thus, the total period of PTO examination delay under 35 U.S.C. § 154(b)(1)(A) is 610 days which is the sum of the period of 14 Month Delay (559 days) and the period of the 4 Month Issue Delay (51 days).

19. Under 35 U.S.C. § 154(b)(1)(B), the plaintiffs are entitled to an additional adjustment of the term of the '892 patent of a period of 345 days, which is the number of days the issue date of the '892 patent exceeds three years from the filing date of the application ("Three Year Delay").

20. 35 U.S.C. § 154(b)(2)(A) states that "to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsections shall not exceed the actual number of days the issuance of the patent was delayed." Of the delays attributable to the PTO for the '892 patent, only the 51 day period delay from December 31, 2006 to February 20, 2007, the 4 Month Issue Delay by the PTO, overlap with the last 51 days of the Three Year Delay period (December 31, 2006 to

February 20, 2007). This overlapping period is not included in the adjustment sought by the plaintiffs.

21. Thus the total period of PTO delay is 904 days which is the sum of the period of PTO examination delay (610 days) and the period of the Three Year Delay (345 days) reduced by the period of overlap (51 days).

22. Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay, which is 148 days as determined by the PTO.

23. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 756 days which is the difference between the total period of PTO delay (904 days) and the period of applicant delay (148 days).

24. On April 20, 2007, patentees timely filed a Request for Reconsideration of Patent Term Adjustment under 37 CFR § 1.705(d) ("Request for Reconsideration") for the '892 patent, requesting that they be granted a corrected final patent term adjustment of 756 days. The Request for Reconsideration is still pending before the PTO.

25. The '892 patent is subject to a terminal disclaimer in which applicants disclaim the terminal part of the '892 patent which would extend beyond the last full day of the statutory term, including any patent term adjustment, granted to the '819 patent.

26. The defendant's denial of the full patent term adjustment of 765 days under 35 U.S.C. § 154(b) for the '892 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

#### **SECOND CLAIM FOR RELIEF**

27. The allegations of paragraphs 1-26 are incorporated herein as if fully set forth.

28. The patent term adjustment for the '819 patent, as determined by defendant under 35 U.S.C. § 154(b), is 492 days as listed on a Certificate of Correction issued on May 1, 2007, by the PTO and attached hereto as Exhibit C. The determination of the 492 day patent term adjustment is in error in that pursuant to 35 U.S.C. § 154(b)(1)(B) the PTO failed to allow an adjustment for the time exceeding three years after the actual filing date to the date when the patent issued. The correct patent term adjustment for the '819 patent is 722 days.

29. The '942 application was filed on December 6, 2001 and the '819 patent issued on March 13, 2007.

30. Under 35 U.S.C. § 154(b)(1)(A), the following periods of time are attributable to PTO examination delay:

- a. A period of 230 days under 35 U.S.C. § 154(b)(1)(A)(i) due to failure by the PTO to mail an action under 35 U.S.C. § 132 not later than 14 months ("14 Month Delay") of the actual filing date of the application (*i.e.* by February 6, 2003).
- b. A period of 14 days under 35 U.S.C. § 154(b)(1)(A)(ii) due to the failure by the PTO to mail a Non-Final Office Action not later than 4 months after applicants submitted a response to a previous action ("4 Month Examination Delay").
- c. A period of 92 days under 35 U.S.C. § 154(b)(1)(A)(iv) due to the failure of the PTO to issue the '819 patent within four months after the date the issue fee was paid ("4 Month Issue delay").
- d. Thus, the total period of PTO examination delay under 35 U.S.C. § 154(b)(1)(A) is 336 days which is the sum of the period of the 14 Month

Delay (230 days), the period of the 4 Month Examination Delay (14 days) and the period of the 4 Month Issue Delay (92 days).

31. Under 35 U.S.C. § 154(b)(1)(B), the plaintiffs are entitled to an additional adjustment of the term of the '819 patent of a period of 827 days, which is the number of days the issue date of the '819 patent exceeds three years from the filing date of the application.

32. Of the delays attributable to the PTO for the '819 patent, only the 14 day period of the 4 Month Examination Delay (September 20, 2005 to October 3, 2005) and the 92 day period of the 4 Month Issue Delay (December 12, 2006 to March 13, 2007) overlap with portions of the Three Year Delay Period (December 7, 2004 to March 13, 2007). These overlapping periods are not included in the adjustment sought by the plaintiffs, pursuant to 35 U.S.C. § 154(b)(2)(A).

33. Thus the total period of PTO delay is 1057 days which is the sum of the period of PTO examination delay (336 days) and the period of the Three Year Delay (827 days) reduced by the period of overlap (14 days + 92 days = 106 days).

34. Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay which is 335 days as determined by the PTO.

35. Accordingly, the correct patent term adjustment under for the '819 patent 35 U.S.C. § 154(b)(1) and (2) is 722 days which is the difference between the total period of PTO delay (1057 days) and the period of applicant delay (335 days).

36. On May 14, 2007, patentees timely filed a Request for Reconsideration of Patent Term Adjustment under 37 CFR § 1.705(d) ("Request for Reconsideration") for the '819 patent requesting that patentees be granted a corrected final patent term adjustment of 722 days. The Request for Reconsideration is pending before the PTO.

37. The defendant's denial of the full patent term adjustment of 722 days under 35 U.S.C. § 154(b) for the '819 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

WHEREFORE, Plaintiffs respectfully pray that this Court:

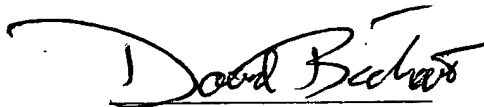
38. Issue an Order changing the period of patent term adjustment for the '892 patent term from 462 days to 756 days and requiring defendant to alter the terms of the '892 patent to reflect the 756 day patent term adjustment, taking into account the terminal disclaimer of the '892 patent.

39. Issue an Order changing the period of patent term adjustment for the '819 patent term from 492 days to 722 days and requiring defendant to alter the terms of the '819 patent to reflect the 722 day patent term adjustment.

40. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: August 16, 2007

Respectfully submitted,



David O. Bickart (DC Bar No. 355313)  
KAYE SCHOLER LLP  
The McPherson Building  
901 Fifteenth Street, N.W., Suite 1100  
Washington, D.C. 20005-2327  
Tel: 202-682-3500  
Fax: 202-682-3580

*Attorneys for Plaintiffs Wyeth and Elan Pharma  
International Limited*



*Of Counsel*

Richard G. Greco

Sapna W. Palla

Kaye Scholer LLP

425 Park Avenue

New York, New York 10022

Tel. (212) 836-8000

Fax. (212) 836-8689

*Attorneys for Plaintiffs Wyeth and  
Elan Pharma International Limited*